

REMARKS

I. STATUS OF CLAIMS

Claims 75-97 are currently pending. No claim is amended herein. Applicants note that in the present Office Action the Examiner has withdrawn the previous rejection of claims 75 and 76 over EP 716,846 (Yamahatsu).

II. REJECTIONS UNDER THE DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING

A. Provisional rejection over pending U.S. App. No. 09/319,165

In an Office Action dated May 9, 2000, the Examiner indicated that then-pending claims 32-74 were rejected under the doctrine of obviousness-type double patenting over claims 25-65 of pending U.S. App. No. 09/319,165. In the latest Office Action, dated April 1, 2003, the Examiner indicated that this rejection is still of record since no terminal disclaimer has been presented. (Office Action dated April 1, 2003, pg. 2.) Applicants respectfully point out that in the last response, filed February 21, 2003, claims 32-74 were cancelled. Accordingly, it is unclear which claims of the current application, if any, are now provisionally rejected in view of claims 25-65 of U.S. App. No. 09/319,165. Applicants respectfully ask for clarification from the Examiner, and for an opportunity to respond to a non-final Office Action should the rejection be applied to any of the currently pending claims.

B. Rejection over U.S. Pat. Nos. 6,241,784 and 6,342,078

The Examiner has rejected claims 75-97 under the doctrine of obviousness-type double patenting over claims 1-28 of U.S. Pat. No. 6,241,784 and over claims 1-50 of U.S. Pat. No. 6,342,078. Applicants respectfully traverse the rejections.

In making an obviousness-type double patenting rejection, the Examiner must compare the claims of the patent and the pending application and decide that the pending claims are an obvious variant of the patent claims, without using the patent disclosure as a reference. M.P.E.P. § 804(II)(B)(1). Importantly, "there must be some clear evidence to establish why the variation would have been obvious" *In re Kaplan*, 229 USPQ 678, 683 (Fed. Cir. 1986). As with a rejection under 35 U.S.C. § 103, in order to establish a prima facie case of obviousness the Examiner must show that all the claim limitations are taught or suggested. MPEP §§ 804, 2143.

With respect to the '784 patent, the Examiner contends that the present claims "are not patentably distinct ... because all of the claims of the ['784] patent are directed to compositions containing the same oxidation dyes, couplers, 2-electron oxidoreductase enzymes and donors for said enzymes as claimed" in the present application. (Office Action dated April 1, 2003, p. 3.) Similarly, with respect to the '078 patent, the Examiner argues that "the ['078] patent claims cover compositions which overlap [with] the instant compositions as the same oxidation bases and couplers are claimed in compositions with 2-electron oxidoreductase enzymes and donors for said enzymes." (*Id.* at lines 17-20.)

However, the Examiner does not contend, and the claims of the '784 and '078 patents do not teach or suggest, "at least one second oxidation base chosen from para-aminophenol, 4-amino-3-methylphenol, 4-amino-3-fluorophenol, 4-amino-3-hydroxymethylphenol, 4-amino-2-methylphenol, 4-amino-2-hydroxymethylphenol, 4-amino-2-methoxymethylphenol, 4-amino-2-aminomethylphenol, 4-amino-2-(β -hydroxyethylaminomethyl)phenol, 4-amino-2-fluorophenol, and acid-addition salts

thereof," as set forth in, for example, pending claim 75. The rejections are clearly deficient because the Examiner does not even address this distinction.

Since the claims of the '784 and '078 patents fail to teach or suggest all the presently claimed limitations, the claims of the patents would not establish a prima facie case of obviousness, and do not support the present obviousness-type double patenting rejections. The fact that the claims of the patents do not foreclose the use of more than one oxidation base is not a teaching or suggestion of a composition comprising a second oxidation base as set forth in, for example, pending claim 75. It is certainly not "clear evidence to establish why the variation would have been obvious" *Kaplan* at 683.

Reconsideration and withdrawal of the rejections are respectfully requested.

III. REJECTIONS UNDER 35 U.S.C. § 103(A)

Claims 75-97 were rejected under 35 U.S.C. § 103(a) over Cotteret in view of Tsujino, and over U.S. Pat. No. 3,884,627 (Brody) in view of Tsujino. Applicants respectfully traverse the rejections, as discussed below. Applicants also submit herewith the Declaration under 37 CFR § 1.132 of Grégory Plos, which provides objective evidence of the nonobviousness of the presently claimed invention.

A. Declaration of Grégory Plos under 37 C.F.R. 1.132

Applicants respectfully submit that evidence of unexpectedly superior chromaticity according to the presently claimed invention renders the presently claimed invention nonobvious. Therefore, although Applicants do not agree that a prima facie case of obviousness has been established (see sections B and C, below), the evidence

of unexpectedly superior results is sufficient to overcome the present rejections under 35 U.S.C. § 103.

The 37 C.F.R. 1.132 Declaration of Grégory Plos filed herewith provides evidence of unexpectedly superior chromaticity according to the presently claimed invention. In particular, as shown in the Plos Declaration, compositions according to the presently claimed invention that comprises

- at least one first oxidation base (N,N-bis(β -hydroxyethyl)-p-phenylenediamine sulfate or 2-(β -hydroxyethyl)-p-phenylenediamine dihydrochloride);
- at least one second oxidation base (4-amino-3-methyl phenol);
- at least one meta-aminophenol coupler (2-methyl-5-amino phenol);
- at least one 2-electron oxidoreductase (uricase); and
- at least one donor for the 2-electron oxidoreductase (uric acid)

yielded unexpectedly superior chromaticity for dyed hair (both natural and permed) as compared to otherwise comparable compositions using hydrogen peroxide as an oxidant instead of the at least one 2-electron oxidoreductase system. See Plos Declaration, compositions B and D (inventive) and compositions A and C (comparative).

More specifically, comparative Composition A comprises a para-phenylenediamine, a para-aminophenol, 2-amino-2-methylpropan-1-ol and water. This composition was diluted with one volume of a 0.3% by weight aqueous solution of hydrogen peroxide. In contrast, inventive Composition B comprises the same ingredients except that it contains uric acid and uricase as an oxidation system in place of hydrogen peroxide. Each of these compositions was applied to locks of natural or

permed gray hair containing 90% white hair. After 30 minutes, the hair was rinsed and its color was measured.

The results of the chromaticity measurements are shown in Table II of the Plos Declaration. As can be seen with respect to a comparison of Compositions A and B, the dyeing system comprising uric acid and uricase provided dyed hair that demonstrated a higher chromaticity than the hair dyed using hydrogen peroxide as an oxidant. For example, the natural hair type dyed with Composition A showed a C* value of 8.9, while the natural hair type dyed with Composition B showed a C* value of 13.6, a increase of over 50%. The same is true of the samples of permed hair dyed with Compositions A and B; the sample dyed with Composition B showed a more than 60% higher chromaticity than that dyed using Composition A. These same qualitative results of superior chromaticity according to the presently claimed invention hold true for compositions utilizing a different para-phenylenediamine, as can be seen in a comparison of Compositions C and D.

These result are not taught or suggested in any of the references of record and would not have been expected by one skilled in the art reading the Tsujino reference. In particular, the Examiner relies on the Tsujino reference for allegedly teaching that enzymatic systems can be used in place of more traditional chemical type oxidants in oxidative hair dyeing compositions. What Tsujino discloses is that "[i]n the present invention, since oxygen in air is activated and utilized, hair damage and skin trouble are less occurred and also the same dyeing and bleaching effects as that by the conventional method may be imparted." Col. 3, lines 22-25 (emphasis added). Thus, if anything were to be expected from Tsujino, it would be the same dyeing and bleaching

effects when using enzymes, and not superior chromaticity as shown in the Plos Declaration. That is, nowhere is it taught or suggested in Tsujino that a dyeing system utilizing an enzymatic oxidant could dye hair with superior chromaticity as compared with systems using a chemical oxidant. In fact, one of ordinary skill in the art reading Tsujino would have had the impression that using an enzymatic dyeing system is a trade-off between an inferior dyeing effect with an alleged, although not certain, decrease in skin irritation associated with the use of a chemical oxidant such as hydrogen peroxide.

The present comparison is appropriate and sufficient evidence of unexpected results for all the present rejections under section 103. In particular, the MPEP expressly advises that "Applicants may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner." MPEP § 716.02(e) (citing *In re Holladay*, 199 USPQ 516 (CCPA 1978).) In this case, since the pair of compositions A and B and the pair of compositions C and D are otherwise the same except for their oxidant, the comparison is at least as close if not closer than any art cited by the Examiner.

For at least this reason, reconsideration and withdrawal of the rejections under section 103 are respectfully requested.

B. Cotteret in view of Tsujino

The Examiner contends that all of the para-phenylenediamines listed in independent claims 75, 76, and 77 are generically encompassed in Cotteret's formula (I) and most are specifically listed in Cotteret at col. 3, lines 1-33. (Office Action dated April 1, 2003, p. 4, lines 16-18.) Furthermore, the Examiner contends that Cotteret's

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aminophenol (a meta-aminophenol coupler as claimed) and at least one para-aminophenol. (*Id.* at lines 20-23.) The Examiner admits, however, that Cotteret does not teach the claimed oxidoreductase enzymes and donors. (*Id.* at p. 5, lines 3-4.) Finally, according to the Examiner, Tsujino teaches that hair dyeing compositions comprising the claimed enzyme/donor system achieve improved characteristics compared to compositions that utilize other oxidation systems. (*Id.* at lines 11-15.) The Examiner further alleges that it would have been obvious to one skilled in the art to combine the teachings of these two references to arrive at the claimed invention.

Applicants disagree with the Examiner and respectfully traverse the rejection for the reasons already of record. See, for example, Responses dated January 9, 2002, and February 21, 2003, the arguments of which are hereby incorporated by reference. Accordingly, Applicants request that the rejection be reconsidered and withdrawn.

C. Brody in view of Tsujino

According to the Examiner, Brody teaches oxidative hair dyeing compositions comprising "three of applicant's claimed first oxidation bases, applicant's claimed second oxidation base and applicant's claimed couplers." (Office Action dated April 1, 2003, p. 7, lines 1-3.) The Examiner admits, however, that, like the Cotteret reference, the Brody reference does not teach or suggest the use of an enzymatic oxidation system in place of the disclosed chemical oxidation system. To make up for this deficiency, the Examiner cites the Tsujino reference for the reasons discussed above. In light of these two teachings, the Examiner argues that the presently claimed compositions and methods would have been obvious to one of ordinary skill in the art.

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Applicants respectfully contend that the disclosure of Brody is similar in nature, and, at most, adds nothing further to the disclosure of Cotteret. Therefore, Applicants incorporate by reference the arguments of record with respect to the rejection over Cotteret in view of Tsujino to the rejection of the claims over Brody in view of Tsujino. For example, see the Response filed February 21, 2003, in which Applicants argued that the rejection over Cotteret in view of Tsujino is improper because, among other things, the Examiner failed to: 1) establish a prima facie case of obviousness; 2) consider the invention as a whole; 3) use the proper standard for obviousness under 35 U.S.C. § 103(a); and 4) not use impermissible hindsight. For all of these reasons of record that are equally applicable to this new rejection, Applicants request that the rejection over Brody in view of Tsujino be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicants submit that the present claims are not rendered obvious in view of the references cited against this application. Applicants therefore request the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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